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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,811	09/17/2003	Kimberly O. Cameron	PC11816A	8747

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
PAVIGLIANITI, ANTHONY JOSEPH	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,811	CAMERON ET AL.	
	Examiner	Art Unit	
	Anthony J. Paviglianiti	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *6-9 and 12-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1 – 15 were pending in the instant application and were subject to the following restriction. **Claims 6 – 9** and **Claims 12 – 15** were withdrawn as being drawn to a non-elected invention (below); accordingly, examination was conducted on **Claims 1 – 5, 10** and **11**.

Election/Restrictions

The Markush groups set forth in the claims include both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. **For these reasons provided below, restriction to one of the following inventions is required under 35 U.S.C. 121,** wherein an Invention is a set of patentably distinct inventions of a broad statutory category (e.g., compounds, methods of use, methods of making, etc.):

I. **Claims 1 – 5, 10 and 11**, drawn to products of formula (I), classified in class 548, subclass 565, and class 546, subclass 153, and other classes and subclasses.

II. **Claims 6 – 9, and 12 – 15,** drawn methods of use of products of formula (I), classified in class 514, subclass 428, and other subclasses.

In addition to an election of one of the above Groups, restriction is further required under 35 U.S.C. §121 as follows:

In accordance with the decisions in In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980) and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App & Int. 1984), restriction of a Markush group is proper where the compounds with the group either (1) do not share a common

utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. §103 with respect to the other member(s).

If **Group I or Group II** is elected, **an election of a single compound is further required**, including an exact definition of each substitution on the base molecule, where a single member at each substituent group is selected. If the base molecule has variable groups $\mathbf{R^1}$, $\mathbf{R^2}$, $\mathbf{R^3}$, $\mathbf{R^4}$, $\mathbf{R^5}$, $\mathbf{R^9}$, $\mathbf{R^a}$, $\mathbf{R^b}$, **Q**, **X**, **Z**, **M**, and **n**, and, for example, **Z** is recited to represent:

> "...-$O(CH_2)_n$-NR^aR^b; -$(CH_2)_n$- NR^aR^b; -CH=CH-C(O)-NR^aR^b; -$(CH_2)_n$-COOH; -CH=CH-COOH; -$O(C_1$-$C_6)$alkyl; -CH=CH-C(O)$O(C_1$-$C_6)$alkyl; and –$(CH_2)_n$-OH; wherein each n is 0 – 5 inclusive, provided that when Z is –O-$(CH_2)_n$-NR^aR^b, n is 2 - 5..."

then Applicant must select a single substituent representing **Z**, **n**, $\mathbf{R^a}$ and $\mathbf{R^b}$ such as "-$O(CH_2)_2$-pyrrolidine," and so on, such that there are specific values representing each subsequent variable and a single compound is identified. One suggestion for the election of a single compound is to select one of the "preferred" embodiments of the invention listed in the Specification on page 10, line 5 through page 12, line 13, or one of Examples 1 – 152 in the Specification on page 44, line 5 through page 93, line 29.

In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds

within the scope of the claim which fall into the same class and subclass as the elected compound, but may also include additional compounds which fall in related subclasses.

Examination will then proceed on the elected compound *and* the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits.

Note that the restriction requirement will not be made final until such time as Applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making the compounds under investigation. This will be set forth by reference to specific class(es) and subclass(es) examined.

Should Applicant traverse on the ground that the compounds are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

All compounds falling outside of the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to non-elected subject matter and will be withdrawn from consideration under 35 U.S.C. §121 and 37 C.F.R. §1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. §121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(i).

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can set forth a group of compounds which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP §608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Group listed above is directed to or involves the use of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP §806.04, MPEP §808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group); i.e., they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in

accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other, because of the following reasons:

Group I and **Group II** are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially-different process of using that product. See MPEP §806.05(h). Applying this rule to the instant case, a method of treating Alzheimer's disease **(Claim 13)**, for example, can be practiced with other, materially different products, such as the cholinesterase inhibitor, donepezil. See, e.g., Cummings, Jeffrey, "Drug Therapy: Alzheimer's Disease," N. Engl. J. Med., vol. 351, pages 56 – 67 (2004), especially at page 61, 1st col., lines 31 – 47. These two inventions (i.e., Groups) are therefore distinct from one another.

In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed upon the examiner to perform a complete search of the defined areas. Therefore, for the reasons given above, the restriction set forth is proper, and not to restrict would impose a serious burden in the examination of this application.

Advisory of Rejoinder

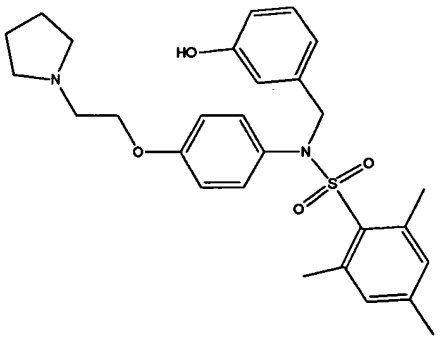
The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election by Applicant:

During a telephone conversation with John Wichtowski, Esq., on March 10, 2005, the above restriction requirements were discussed, and an election was made, without traverse, of **Group I,** and an election of the compound N-(3-hydroxy-benzyl)-2,4,6-trimethyl-N-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl] benzenesulfonamide, which has the chemical structure:



(Example 109, page 76, lines 21 – 23). In making the election, Mr. Wichtowski expressly reserved the right to rejoin "method of use" claims for examination for the purpose of patentability if a product claim is found to be allowable.

Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed. 37 C.F.R. §1.143. Applicant is further advised that a reply to this requirement must include an identification of the specific compound that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

In accordance with MPEP §821.04 and In re Ochiai, *supra*, process claims which are commensurate in scope with the allowed product claims will be rejoined (following a finding that one or more product claims are allowable) and examined for patentability, including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

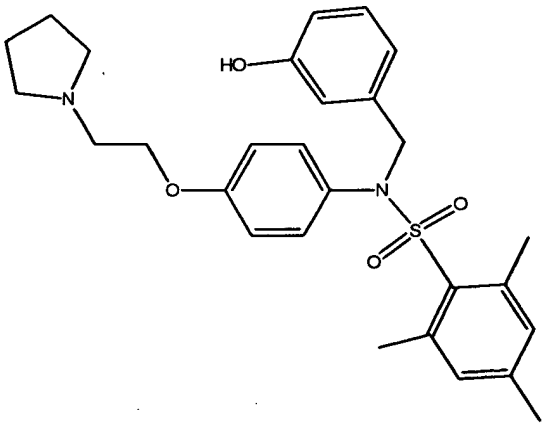
Claims 6 – 9 and **Claims 12 – 15** were withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to a non-elected invention.

Analysis of Claims 1 – 5, 10 and 11 (Prior Art Searched)

The invention was searched as follows:

1) Elected Compound

The elected compound, N-(3-hydroxy-benzyl)-2,4,6-trimethyl-N-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl] benzenesulfonamide, which has the chemical structure:



, was searched and appears to be free of the prior art.

2) Expansion of search to compounds within same patent classification as elected invention

The search of the prior art was expanded to include compounds in the same patent classification and subclassification group as the elected compound. The determinant of patent classification for the elected species was the "pyrrolidine" group on substituent "**Z**."

Specifically, the search of the prior art was expanded several times, resulting in the following which appeared to be free of the prior art of record:

$\mathbf{R^1}$, $\mathbf{R^2}$, $\mathbf{R^3}$ represents H, -OH, F, Cl, Br, I, methyl, ethyl, propyl, and butyl;

X represents *either* C=O *or* SO_2;

$\mathbf{R^4}$ represents H, C_1-C_5 alkyl, C_2-C_6 alkenyl, or C_2-C_6 alkynyl;

$\mathbf{R^5}$ represents *either* $-(CH_2)_n$-phenyl [as in the elected species] *or* $-(CH_2)_n$-naphthyl, where **n** was 0, 1, 2, 3, 4, 5, 6 or 7 and where the phenyl or naphthyl ring was optionally substituted by hydrogen, hydroxy, halogen, cyano, C_1-C_5 alkyl, or amino group(s);

Q represents a benzene ring, which is required to be substituted by **Z** (to avoid prior art);

Z represents $-O(CH_2)_n$-pyrrolidine (bound via the ring nitrogen) or $-O(CH_2)_n$-piperidine (bound via the ring nitrogen).

3) Expansion of search for 39 individually-claimed chemical species in Claim 5

The thirty-nine individually-claimed chemical compounds in **Claim 5** were searched and appear to be free of the prior art; however, species #10 of Claim 5 was rejected for not being a further limitation of Claim 1 (see rejection under 35 U.S.C. §112 below).

Claim Rejections - 35 USC § 102

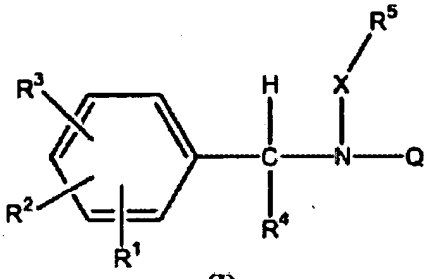
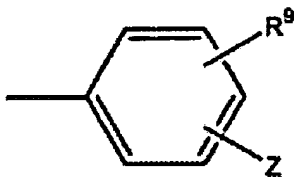
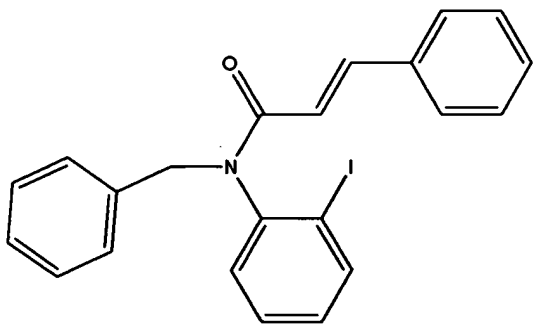
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Tetrahedron Letters - 1988 (Bowman)

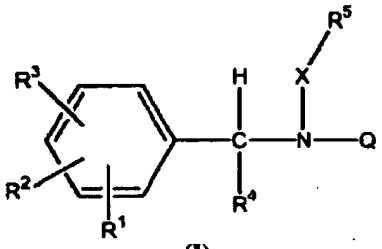
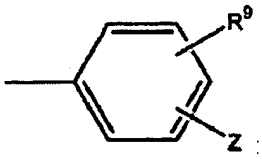
Claims 1, 2, 3 and **4** of the present invention are rejected under 35 U.S.C. 102(b) as being anticipated by the article by W. Russell Bowman, et al., "Synthesis of Oxindoles by Radical Cyclisation," Tetrahedron Letters, vol. 29(50), pages 6657-6660 (1988), which discloses chemical species which directly anticipate the genus structure of formula (I) depicted in **Claim 1** and each of its additional limitations in **Claims 2, 3** and **4**.

Claim 1 of the present invention claims species of the following chemical genus structure:  (I) , where **Q** is  , while **Claims 2, 3** and **4** further limit the values of **Q**, **X**, $\mathbf{R^5}$, $\mathbf{R^1}$, $\mathbf{R^2}$, $\mathbf{R^3}$, **R9**, **Ra** and $\mathbf{R^b}$. This genus of compounds is anticipated by the Ishikawa reference, however, where $\mathbf{R^1}$, $\mathbf{R^2}$, $\mathbf{R^3}$ and $\mathbf{R^4}$ are H; **X** is C=O; **Q** is phenyl, substituted with $\mathbf{R^9}$ which is an iodo group; and $\mathbf{R^5}$ is either (1) –CH=CH-phenyl; yielding the following compound: N-(2-iodopenyl)-3—phenyl-N-(phenylmethyl)-2-propenamide,  , previously disclosed in Bowman,

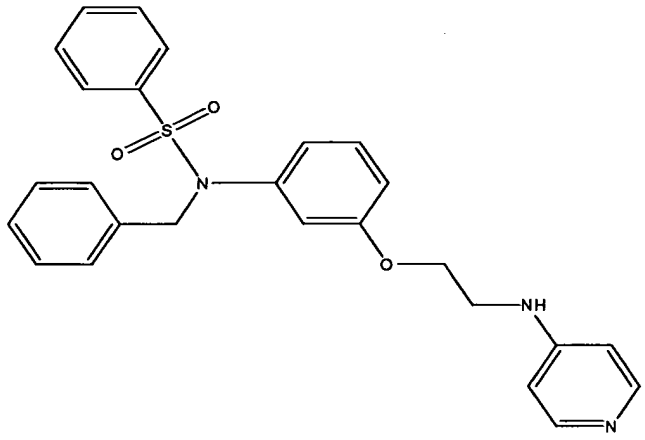
W.R., et al., "Synthesis of Oxindoles by Radical Cyclisation," Tetrahedron Letters, vol. 29(50), pages 6657-6660 (1988) at page 6659, lines 1 - 3 ("...when the N-methyl group of (I) was replaced by a N-benzyl group, a 88% yield of the analogous exo-compound was obtained, indicating that other N-alkyl groups are acceptable"). This chemical compound also anticipates each of the limitations in **Claims 2, 3** and **4** of the present invention, such as where $\mathbf{R^5}$ is "–(ethenyl)-**M**, wherein **M** is ...phenyl."

2) WO 94/20467 (Von Der Saal)

Claims 1, 4, 10 and **11** are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/20467 (published September 15, 1994) by inventor Wolfgang Von Der Saal, et al., which discloses three species which directly anticipate the genus structure of formula (I) depicted in **Claim 1** (including the additional limitations in **Claims 2** and **4**), as well as the pharmaceutical compositions of **Claims 10** and **11**. This reference was (properly) listed by applicant on the Information Disclosure Statement.

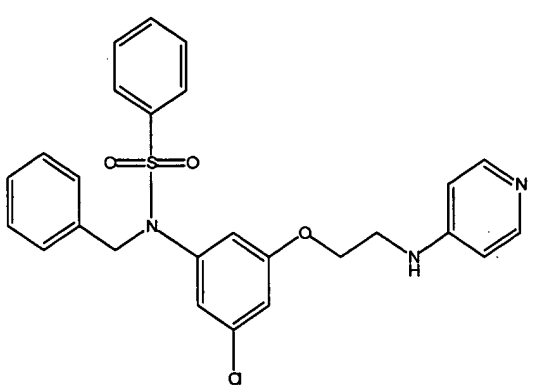
Claim 1 of the present invention claims species of the following chemical genus structure:  **(I)**, where **Q** is  . This genus of compounds is anticipated by the Von Der Saal reference, however, where $\mathbf{R^1}$, $\mathbf{R^2}$, $\mathbf{R^3}$ and $\mathbf{R^4}$ are H; **X** is SO_2; $\mathbf{R^5}$ is phenyl; **Q** is phenyl and **Z** is $-O(CH_2)_2NH$-4-pyridine, yielding the following

compound previously disclosed in Von Der Saal's patent application as Example 15:

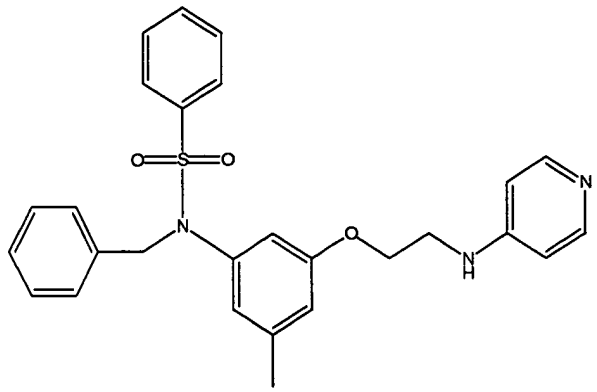


N-benzyl-N-{3-[2-(pyridin-4-ylamino)-ethoxy]phenyl}-benzenesulfonamide (WO 94/20467, p. 35, lines 9 - 18).

Two other compounds in the Von Der Saal patent application publication WO 94/02467 also anticipate the genus structure claimed in the present invention. The claimed invention permits **Q** to be substituted by $\mathbf{R^9}$ *and/or* **Z** (p. 128, lines 9 – 11) [emphasis added]; therefore, where $\mathbf{R^1}$, $\mathbf{R^2}$, $\mathbf{R^3}$ and $\mathbf{R^4}$ are H; **X** is SO_2; $\mathbf{R^5}$ is phenyl; **Q** is phenyl; **Z** is $-O(CH_2)_2NH$-4-pyridine; and $\mathbf{R^9}$ is *chlorine* or *methyl*, respectively, the compounds which result were previously disclosed in WO 94/02467 as "Example 88" (page 70 lines 1 - 17) and Example 91 (p. 72, lines 23 – 27) respectively:



N-benzyl-N-{3-[2-(pyridin-4-ylamino)-ethoxy]5-chlor-phenyl}-benzenesulfonamide

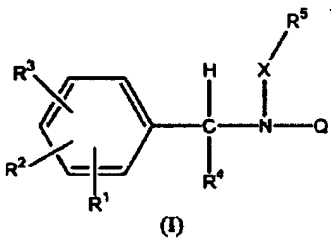
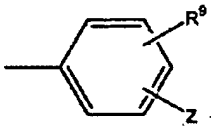


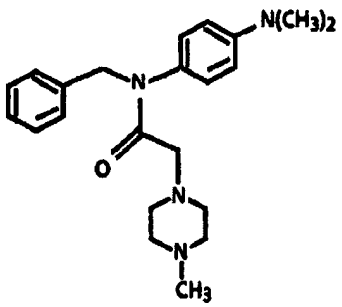
N-benzyl-N-{3-[2-(pyridin-4-ylamino)-ethoxy]5-methyl-phenyl}-benzenesulfonamide

Claims 10 and 11 of the present invention are therefore also anticipated by WO 94/02467 (Van Der Saal), which disclosed "...the hydrates, solvates and physiologically acceptable salts of these compounds...medicaments containing said compounds and the use of said compounds for producing medicaments." (WO 94/02467 at Abstract, lines 15 – 16).

3) EP 0 585 500 A1 (Van Hijfte)

Claims 1 and **10** of the present invention are rejected under 35 U.S.C. 102(b) as being anticipated by European Application EP 0 585 500 A1 (published March 9, 1994), by inventor Luc van Hijfte, et al., which discloses chemical species which directly anticipate the genus structure of formula (I) in **Claim 1** as well as the pharmaceutical compositions of **Claim 10**.

Claim 1 of the present invention claims species of the following chemical genus structure:  (I), where **Q** is  . This genus of compounds is anticipated by the Van Hijfte reference, however, where $\mathbf{R^1}$, $\mathbf{R^2}$, $\mathbf{R^3}$ and $\mathbf{R^4}$ are H; **X** is C=O; $\mathbf{R^5}$ is 4-methyl-piperazine; **Q** is phenyl; **n** = 0; and **Z** = NR^aR^b where R^a and R^b are each a methyl group, yielding the following compound previously disclosed in Van Hijfte's patent application, N-4-dimethylaminophenyl-N-benzyl-4-methyl-1-piperazineacetamide:

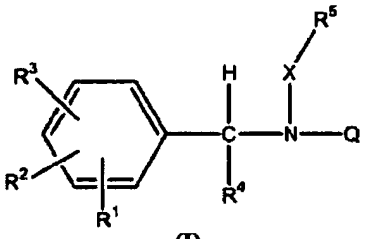
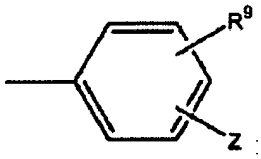


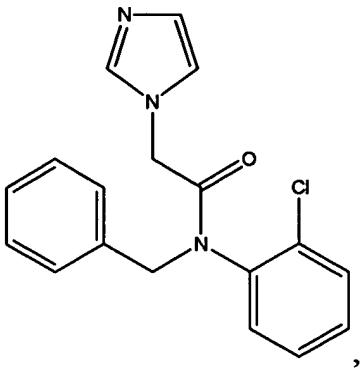
(EP 0 585 500 A1, "Example 53," p. 43, lines 1 – 18).

Claim 10 of the present invention are therefore also anticipated by EP 0 585 500 A1 (Van Hijfte), at page 54, lines 3 – 4, which disclosed "a pharmaceutical composition comprising the compound according to claim 1, optionally in combination with a pharmaceutically acceptable carrier."

4) <u>JP 04-145067 (Ishikawa)</u>

Claims 1 and **2** of the present invention are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent JP 04-145067 A2 (published May 19, 1992), by inventor Hiromichi Ishikawa, et al., which discloses chemical species which directly anticipate the genus structure of formula (I) depicted in **Claim 1** and its additional limitations of **Claim 2**.

Claim 1 of the present invention claims species of the following chemical genus structure:  (I) , where **Q** is  , while **Claim 2** limits the values of **Q**, $\mathbf{R^5}$, $\mathbf{R^a}$ and $\mathbf{R^b}$. This genus of compounds is anticipated by the <u>Ishikawa</u> reference, however, where $\mathbf{R^1}$, $\mathbf{R^2}$, $\mathbf{R^3}$ and $\mathbf{R^4}$ are H; **X** is C=O; **Q** is phenyl, substituted with $\mathbf{R^9}$ which is either a (1) methyl or (2) chloro group; and $\mathbf{R^5}$ is either (1) -CH_2-piperidine (bonded via the nitrogen atom), (2) -CH_2-azepine (7-membered ring bonded via the nitrogen atom); (3) -CH_2-pyrazole; (4) CH_2-1,2,4-triazole; and (5) -CH_2-imidazole; yielding, for example, the following compound: N-(2-chlorophenyl)-N-(phenylmethyl)-1H-imidazole-1-acetamide,

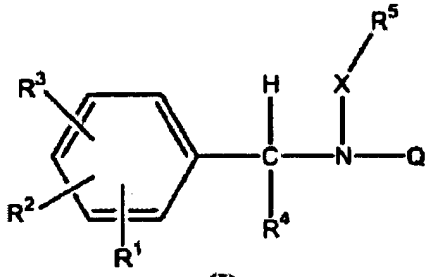


, previously disclosed in Ishikawa's patent (JP 04-145067, page 2, col. 2, line 21 "compound 8"). See also JP 04-145067 A2, page 2, col. 1 & 2, compounds 1 – 16. These chemical species, compounds 1 – 16, also anticipate the limitations in **Claim 2** of the present invention.

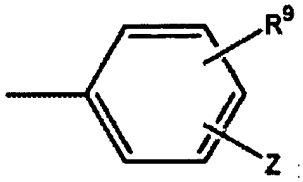
5) Journal of Medicinal Chemistry – 1983 (Linfield)

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Warner Linfield, et al., "Antibacterially active Substituted Anilides of Carboxylic and Sulfonic Acids," J. Med. Chem., vol. 26(12), pages 1741-1746 (December 1983).

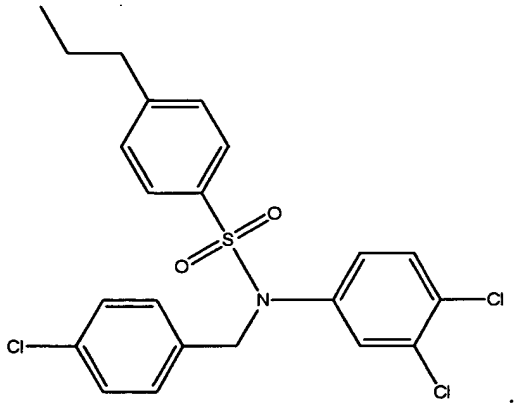
Claim 1 of the present invention claims species of the following chemical genus structure:



(I)



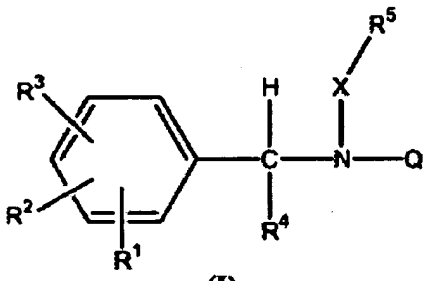
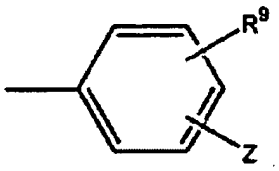
, where **Q** is . This genus of compounds is anticipated by the Linfield reference, however, where $\mathbf{R^1}$ is chlorine; $\mathbf{R^2}$, $\mathbf{R^3}$ and $\mathbf{R^4}$ are H; **X** is SO_2; $\mathbf{R^5}$ is phenyl, substituted by n-propyl; **Q** is phenyl; and $\mathbf{R^9}$ is chlorine, which yields the compound previously disclosed in Linfield's article at page 1743, Table IV, compound

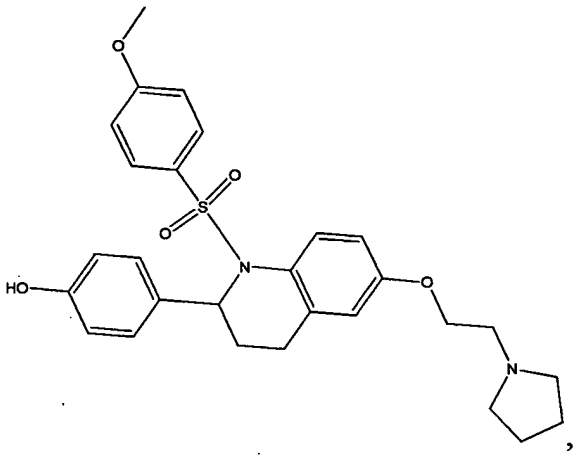
105, which has the structure:  . This species therefore anticipates the limitations of **Claim 1** of the present invention.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 (species #10) is rejected pursuant to 35 U.S.C. §112, 2nd paragraph, for lack of antecedent basis, because it recites the limitation, "A compound of claim 1 selected from the group consisting of...4-[1-(4methoxy-benzenesulfonyl)-6-(2-pyrrolidin-1-yl-ethoxy) –1,2,3,4-tetrahydro-quinolin-2-yl]-phenol." There is insufficient antecedent basis for this limitation in **Claim 5, species #10**, as its chemical structure is not within the genus of compounds claimed by **Claim 1**; in particular, that **Claim 1** of the present invention claims species of the following chemical genus structure:  **(I)** , where **Q** is  ,

while **Claim 5, species #10** has the structure:  , (i.e., **Q** is "tetrahydro-quinoline"), which is not among the genus group's definition for N---Q in **Claim 1**.

This rejection would be obviated by deleting **species # 10** from the thirty-nine species claimed in **Claim 5**.

Claim 2 is rejected pursuant to 35 U.S.C. §112, 2nd paragraph, for lack of antecedent basis, because it recites the limitation, "A compound of claim 1, wherein...$\mathbf{R^5}$ is ...-$(CH_2)_n$-**M**...where **M** is...phenyl," but **Claim 1**'s definition of $\mathbf{R^5}$ does not encompass phenyl. Specifically, **Claim 1** defines $\mathbf{R^5}$ as "...-$(CH_2)_n$-**M**...wherein n is 0-5...and wherein **M** is...(i) a fully saturated 3-8 membered ring, or a partially saturated, or fully saturated 5-8 membered ring..." Because phenyl is a fully *unsaturated* ring, dependent **Claim 2**'s definition of **M** as "phenyl" lacks an antecedent basis in **Claim 1**.

Claim 3 is also rejected pursuant to 35 U.S.C. §112, 2nd paragraph, for lack of antecedent basis, because it recites the limitation, "A compound of claim 1, wherein...$\mathbf{R^5}$ is ...-(ethenyl)-**M** or -**M**...where **M** is...phenyl," but **Claim 1**'s definition of $\mathbf{R^5}$ does not encompass phenyl. Specifically, **Claim 1** defines $\mathbf{R^5}$ as "...-$(CH_2)_n$-**M**...wherein **n** is 0-5...and wherein **M** is...(i) a fully saturated 3-8 membered ring, or a partially saturated, or fully saturated 5-8 membered

ring..." Because phenyl is a fully *unsaturated* ring, dependent **Claim 3**'s definition of **M** as "phenyl" lacks an antecedent basis in **Claim 1**.

Claim 4 is similarly rejected pursuant to 35 U.S.C. §112, 2nd paragraph, for lack of antecedent basis, because it recites the limitation, "A compound of claim 1, wherein...$\mathbf{R^5}$ is ... phenyl," but **Claim 1**'s definition of $\mathbf{R^5}$, as before, does not encompass phenyl. Specifically, **Claim 1** defines $\mathbf{R^5}$ as "...-$(CH_2)_n$-**M**...wherein **n** is 0-5...and wherein **M** is...(i) a fully saturated 3-8 membered ring, or a partially saturated, or fully saturated 5-8 membered ring..." Because phenyl is a fully *unsaturated* ring, dependent **Claim 4**'s definition of $\mathbf{R^5}$ as "phenyl" lacks an antecedent basis in **Claim 1**.

A suggestion to overcome the foregoing rejections brought pursuant to 35 U.S.C. §112, 2nd paragraph, would be to amend Claim 1 on page 128, line 22, to recite, "(i) a fully saturated 3-8 membered ring, or a partially saturated, or fully *unsaturated* 5-8 membered ring..." [i.e., if this is the inventors' intention]. Although the Specification does not provide support for this amendment, *verbatim*, the majority of the species in the claims and the examples of compounds in the Specification have phenyl groups at the $\mathbf{R^5}$ position and thereby provide support.

Although **Claims 6 – 9** and **Claims 12 – 15** were withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to a non-elected invention, please note when amending claims that there appears to be an error in non-elected **Claim 15**, which recites the "*composition* of claim 8," even though **Claim 8** is a "method of use" claim.

Conclusion

Claims 1 – 4, 10 and **11** were rejected pursuant to 35 U.S.C. §102(b).

Claim 5 was rejected pursuant to 35 U.S.C. §112, 2nd paragraph.

Claims 6 – 9 and **Claims 12 – 15** were withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to a non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is **(571) 272-3107**. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, may be reached at (571) 272-0699. **The FAX phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Please note that this is a new central FAX number for all official correspondence.**

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Anthony J. Paviglianiti
Patent Examiner
TC-1600, Art Unit 1626

Joseph K. McKane
Supervisory Patent Examiner
TC-1600, Art Unit 1626